103D CONGRESS
1ST SESSION

S. 672

To amend the Federal Food, Drug, and Cosmetic Act to regulate the sale and distribution of tobacco products containing tar, nicotine, additives, carbon monoxide, and other potentially harmful constituents, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 30 (legislative day, MARCH 3), 1993

Mr. BINGAMAN (for himself, Mr. CHAFEE, Mr. BRADLEY, and Mr. PELL) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to regulate the sale and distribution of tobacco products containing tar, nicotine, additives, carbon monoxide, and other potentially harmful constituents, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Tobacco Health and Safety Act''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment

to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. FINDINGS.

The Congress finds that—

(1) cigarette smoking and the use of smokeless tobacco products continue to represent a major health hazard to the American public,

(2) cigarette smoking continues to be the single most preventable cause of death and disability in the United States,

(3) tobacco products contain hazardous tobacco additives, gases, and other chemical constituents dangerous to health,

(4) the use of tobacco products cost the United States in excess of $60,000,000,000 in lost productivity and health care costs,

(5) tobacco products contain nicotine, a poisonous addictive drug,

(6) the tobacco industry has maintained that smoking is an adult practice and that smoking and the use of smokeless tobacco is not a practice to be carried out by young people,

(7) 60 percent of all new smokers are under the age of 14 years of age,

(8) despite the known adverse health effects associated with tobacco, it remains one of the least regulated consumer products,

(9) in one year alone, 1990, the tobacco industry spent more than $4,000,000,000 to promote and sell its products,

(10) the Congress of the United States has a major policy-setting role in ensuring that the use of tobacco products is discouraged to the maximum extent possible, and

(11) creation of a separate chapter for tobacco under the Federal Food, Drug, and Cosmetic Act assures the most effective means of regulating the product without the product being banned.

SEC. 3. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended by adding at the end thereof the following new paragraphs:

''(bb) The term 'tobacco product' means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff, and chewing tobacco.

''(cc) The term 'tobacco additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any tobacco product.

''(dd) The term 'constituent' means any element of cigarette mainstream or sidestream smoke which is present in quantities which represent a potential health hazard or where health effect is unknown.

''(ee) The term 'tar' means mainstream total articulate matter minus nicotine and water.''.

SEC. 4. ENFORCEMENT.

Section 301 (21 U.S.C. 331) is amended by adding at the end thereof the following new subsection:

''(t) The sale or distribution of tobacco products in violation of section 701 and the manufacture, importation, or packaging of tobacco products in violation of section 705.''.

SEC. 5. REGULATION.

(a) REGULATION.—The Federal Food, Drug, and Cosmetic Act is amended by redesignating chapters VII, VIII, and IX as chapters VIII, IX, and X, respectively, and by adding after chapter VI the following:

''CHAPTER VII—TOBACCO PRODUCTS

''PROHIBITED ACTS

''SEC. 701. (a) It shall be unlawful for a tobacco product intended for use by man which contains nicotine or tobacco additives or, because of its pharmacological and toxicological effects or other potentiality for harmful effects, presents risks to health—

''(1) to be sold to any person under the age of 18 years or under such other age, greater than 18, as the State in which the sale occurs may by law establish,

''(2) to be distributed if the product is misbranded as prescribed by section 702,

''(3) to be distributed if the product is adulterated as prescribed by section 703, or

''(4) to be distributed as a free sample or to be made available as the result of coupons or other materials which allow for the obtaining of free or discounted tobacco products.

''(b)(1) In carrying out the requirements of subsection (a)(1), States shall enact such laws and promulgate such regulations as may be necessary to ensure compliance.

''(2) If the Secretary finds that—

''(A) the implementation and enforcement of State laws and regulations is insufficient to require compliance with the requirement of subsection (a)(1), and

''(B) Federal regulation will provide the only reasonable assurance of the inaccessibility of tobacco products to those who are lawfully prohibited from purchasing such products, the Secretary may, to as-

sist in enforcing such requirement, by regulation impose requirements on the form, manner, or location of the sale of tobacco products in such State or on any combination of such aspects of the sale of tobacco products. A tobacco product which is sold or distributed in violation of subsection (a)(1) or (a)(4) shall be considered a misbranded tobacco product.

''MISBRANDED TOBACCO PRODUCTS

''SEC. 702. (a) A tobacco product shall be deemed to be misbranded—

''(1) if its labeling is false or misleading in any particular,

''(2) if the labeling fails to contain the statements required by section 4 of the Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 et. seq.),

''(3) if the labeling fails to contain the statement 'Federal Law Prohibits Sale to Minors' in a prominent and conspicuous place as prescribed by regulation by the Secretary,

''(4) if in package form, unless it bears a label containing—

''(A) the name and place of business of the manufacturer, packer, or distributor, and

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count,

except that under regulations of the Secretary reasonable variations from the requirements of this paragraph shall be permitted and exemptions from such requirements for small packages shall be established,

''(5) if the manufacturer, importer, or packager of the product does not provide the list of tobacco additives contained in the product in accordance with section 704(a),

''(6) if it does not disclose the tobacco additives contained in the product as required under section 704(b), or

''(7) if it does not disclose tar, nicotine, carbon monoxide, and other constituents as required under section 705.

''(b) The Secretary may by regulation require that the manufacturer of tobacco products provide consumers of tobacco products with additional information, by way of additional labeling of packages, requiring inserts or other means, about the adverse effects of tobacco products, adequate warnings and directions for use, contraindications, adequate warnings against use in pathological

conditions, and any information deemed necessary by the Secretary.

''(c)(1) Nothing in this chapter or the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 et seq.) shall prohibit a manufacturer of tobacco products from providing consumers with information about the adverse effects of tobacco products in addition to the information they are required to provide pursuant to this chapter and the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 et seq.).

''(2) The Secretary shall have the authority to modify existing warning labels as required by the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act so long as such modifications do not weaken the health message contained in such warnings.

''ADULTERATED TOBACCO PRODUCTS

''SEC. 703. A tobacco product shall be deemed to be adulterated—

''(1) if the level of any tobacco additive contained in the product is in violation of a requirement under section 704(b),

''(2) if the nicotine, tar, carbon monoxide, or other harmful constituent level has not been established under section 705,

''(3) if it bears or contains any added poisonous or deleterious substance which may render it injurious to health,

''(4) if it contains in whole or in part any filthy, putrid, or decomposed substance,

''(5) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health, or

''(6) if its container or packaging is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.

''TOBACCO ADDITIVES

''SEC. 704. (a) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any tobacco product unless such person has provided to the Secretary a complete list of each tobacco additive used in the manufacture of such tobacco product and the relative quantity of such additive.

''(b)(1) The Secretary shall by regulation prescribe any disclosure requirements on packages of tobacco products or by any other means in order to adequately inform the public of the tobacco additives contained in tobacco products.

''(2) If the Secretary determines that any tobacco additive in a tobacco product, either by itself or in conjunction with any other additive, is unsafe and presents unnecessary increased risks to health, the Secretary may require that such levels of the tobacco additive in the tobacco product be reduced or that it be prohibited from use. The Secretary may make such a determination only with the advice of experts qualified by scientific training and experience to evaluate the safety of tobacco additives.

''NICOTINE, TAR, CARBON MONOXIDE, AND OTHER CONSTITUENTS

''SEC. 705. (a) It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any tobacco product unless such person has provided the Secretary with a complete list of all brands of such tobacco products and until such products have been tested by the Secretary to establish the tar, nicotine, carbon monoxide, and other constituent (as determined by the Secretary) levels for each brand.

''(b) The Secretary may by regulation prescribe any disclosure requirements on packages of tobacco products or by any other means to adequately inform the public of the quantities and levels of nicotine, tar, carbon monoxide, or other constituents and initiate and carry out any educational activities to adequately inform the public that any reduced levels of nicotine, tar, carbon monoxide, or

other constituents do not necessarily constitute a reduced health risk.

''REPORTS

''SEC. 706. The Secretary shall report annually to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on—

''(1) the use of tobacco additives in tobacco products, including a list of tobacco additives which have been prohibited from use in tobacco products,

''(2) the levels of nicotine, tar, carbon monoxide, and other potentially harmful constituents in tobacco products or tobacco smoke and any actions the Secretary has taken to reduce the levels of these constituents, and

''(3) any legislative recommendations that would further reduce the risk to health associated with the use of tobacco products, tobacco additives, nicotine, tar, or other potentially harmful constituents.''.

(b) CONFORMING AMENDMENTS.—Sections 701 through 709 are redesignated as sections 801 through 809, respectively, sections 801 and 802 are redesignated as sections 901 and 902, respectively, and sections 901 and 902 are redesignated as sections 1001 and 1002, respectively.

SEC. 6. WARNING LABELS.

Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) is amended by striking out in paragraphs (1), (2), and (3) the phrase ''SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide,'' and inserting in lieu thereof the following: ''SURGEON GENERAL'S WARNING: Smoking is Addictive. Once you start you may not be able to stop.''

SEC. 7. NONTOBACCO NICOTINE CONTAINING PRODUCTS.

Any product which contains nicotine but does not meet the definition of tobacco products as contained in section 201(bb) of the Federal Food, Drug, and Cosmetic Act shall be deemed to be a drug under section 201(g)(1)(C) of such Act.

SEC. 8. MISCELLANEOUS.

(a) CONSTRUCTION.—Nothing in the amendment made by section 5 shall supersede, repeal, or modify any requirement of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 et. seq.).

(b) EFFECTIVE DATE.—The amendments made by this Act shall be effective 6 months after date of enactment.

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